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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/743,687	12/19/2003	Jeffrey A. Hubbell	158264-0003	7788	
29000	7590 06/30/2004		EXAMINER		
IRELL & MANELLA LLP 1800 AVENUE OF THE STARS			SZEKELY, PETER A		
SUITE 900		ART UNIT	PAPER NUMBER		
LOS ANGELI	ES, CA 90067		1714		
			DATE MAILED: 06/30/2004	DATE MAILED: 06/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
		10/743,687	HUBBELL ET AL.			
Office Action Summary		Examiner	Art Unit			
	-	Peter Szekely	1714			
	The MAILING DATE of this communication ap	· ·				
Period fo						
THE - External after - If the - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be ti ly within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS fron e, cause the application to become ABANDON!	imely filed bys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 19 L	December 2003.				
2a)□	This action is FINAL . 2b)⊠ This	s action is non-final.				
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
4) 🖂	Claim(s) 19 is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)[☐ Claim(s) is/are allowed. ☐ Claim(s) <u>19</u> is/are rejected.					
6)⊠						
7)	Claim(s) is/are objected to.					
8)[Claim(s) are subject to restriction and/o	or election requirement.				
Applicati	on Papers					
9)	The specification is objected to by the Examin	er.				
,)⊠ The drawing(s) filed on <u>19 December 2003</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11)	The oath or declaration is objected to by the E	xaminer. Note the attached Office	e Action or form PTO-152.			
Priority u	ınder 35 U.S.C. § 119					
12)	Acknowledgment is made of a claim for foreigr	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).			
-	☐ All b)☐ Some * c)☐ None of:		, , , ,			
1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documen	ts have been received in Applicat	tion No			
	3. \square Copies of the certified copies of the price	ority documents have been receiv	ed in this National Stage			
	application from the International Burea	, , , ,				
* S	See the attached detailed Office action for a list	of the certified copies not receiv	ed.			
Attachmen			(070,440)			
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D				
3) 🛛 Inforr	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>6/24/04</u> .		Patent Application (PTO-152)			

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DETAILED ACTION

Priority.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Since U.S. Patent Applications 07/870,540 (abandoned), 07/958,870 (U.S. Patent 5,529,914), 08/022,687 (U.S. Patent 5,410,016), 08/336,393 (U.S. Patent 5,820,882) and 08/379,848 (U.S. Patent 5,626,863), do not contain any subject matter regarding a biocompatible mixture containing at least one ionically crosslinkable component and at least one covalently crosslinkable component, the effective filing date of the instant application is August 1, 1995. The claimed subject matter has to be present in every link of the continuation chain in order to establish priority. Applicants cannot jump over the gaps and reach back for subject matter into earlier applications, which they have given up by failing to incorporate it in subsequent specifications. Furthermore, the patent numbers of those applications, which have matured into U.S. Patents, should be included in the first paragraph of the instant application and abandonments should also be noted in the same place.

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Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Nisshinbo Industries Inc. EP 0 555 980.
- 3. Nisshinbo discloses a water-soluble polymer and an oligosaccharide in the Abstract, and ionic and covalent crosslinking on page 3, lines 15-16. Applicants' claim is not novel.
- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
- 5. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al. 5,334,640, Desai et al. 5,550,178, Soon-Shiong et al. 5,705,270, Soon-Shiong et al. 5,700,848, Gunther et al. 5,736,595, Soon-Shiong et al. 5,837,747, Soon-Shiong et al. 5,846,530 or Mathiowitz et al. 5,985,254

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6. Desai et al. ('640) teach applicants' invention in claim 1. The contents of Desai et al. ('178) are similar. Soon-Shiong et al. recite microcapsules in claim 1, polysaccharides in claim 5, ionically and covalently crosslinked biocompatible material in claim 9. The contents of the other three Soon-Shiong et al. patents are similar. Gunther et al. divulge a polysaccharide, a water-soluble monomer, and ionic and covalent crosslinking agents in the Abstract. Mathiowitz et al. reveal ionically and covalently crosslinkable polymers in column 3, lines 6-7, and polysaccharides in column 4, lines 48-49. Applicants' claim is not novel.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain <u>a</u> patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 8. Claim 19 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 19 of prior U.S. Patent No. 5,334,640. This is a double patenting rejection.

 One common inventor or a common assignee is sufficient for this rejection. The inventive entity does not have to be the same.
- 9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 10. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-58 of U.S. Patent No. 5,334,640 C1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Reexamination Certificate discloses the species for the application's genus. One common inventor or a common assignee is sufficient for this rejection. The inventive entity does not have to be identical.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Szekely whose telephone number is 703-308-2460. The examiner can normally be reached on Tuesday-Friday 7:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 703-306-2777. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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Peter Szekely Primary Examiner Art Unit 1714

P.S. June 24, 2004.